AMENDMENTS TO THE CLAIMS

Complete listing of all claims, with status identifiers, as Amended by this Preliminary Amendment

(added text shown with underlining; deleted text shown ~~by strikethrough~~)

1. (CURRENTLY AMENDED) A pharmaceutical preparation suitable for use in the eye, which comprises:

(i) a pharmaceutically-acceptable carrier suitable for use in the eye;

(ii) one or more ingredients selected from factors and agents that promote any one or more of survival, health, cell attachment and normal differentiation of ocular surface epithelial cells and optionally factors and agents that prevent squamous metaplasia;

(iii) one or more agents capable of altering the fluid properties of a ~~establishing~~ tear film including at least one agent capable of establishing ~~and/~~or maintaining a stable tear film and optionally one or more agents selected from the group consisting of ophthalmological lubricating agents, viscosity enhancing agents and agents capable of reducing tear film evaporation;

and wherein the factors and agents in components (ii) and (iii) ~~being~~ are synthetic or recombinant or licensed for pharmaceutical use.

2. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim 1, further comprising:

(iv) one or more agents suitable for use in the treatment or prophylaxis of an ocular surface disease, disorder, or damage.

3. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim 1 ~~or claim 2,~~ further comprising:

(v) one or more ingredients selected from the group consisting of factors and agents that promote ~~any one or more of~~ survival and maintenance of stem cell characteristics, growth of ocular surface stem cells, and survival, maintenance and differentiation of stem cell offspring *in vitro* or *in vivo,* and wherein the factors and agents ~~being~~ are synthetic or recombinant or licensed for pharmaceutical use.

4. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim 2 ~~or claim 3~~, wherein the one or more of the agents (iv) suitable for use in the treatment or prophylaxis of an ocular surface disease, disorder or damage is selected from the group consisting of:

mydriatics agents, steroids, mucolytic agents, inhibitors of angiogenesis, attachment factors, antifibrotic agents, antimicrobial agents, ~~anti-glucoma~~ anti-glaucoma agents, and agents that reduce the accumulation of toxic by-products of cell metabolism.

5. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 4~~ claim 1, wherein component (i) comprises one or more agents selected from the group consisting of:

purified water for eye drops, cream bases for ophthalmological compositions, gel bases for ophthalmological compositions and ointment bases for ophthalmological compositions.

6. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 5~~ claim 1, wherein component (ii) comprises one or more agents selected from the group consisting of:

agents that provide a metabolisable source of carbon, amino acids, growth factors, vitamins, antioxidants, mucin substitutes, bulk ions, trace elements, proteins, hormones, protease inhibitors, and anti-microbial agents.

7. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 6~~ claim 1, wherein [[an]] the agent capable of establishing ~~and/~~or maintaining a stable tear film is selected from the group consisting of:

lipids, lipoproteins, and meibomian gland secretions, and synthetic analogues thereof.

8. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 7~~ claim 1, wherein ~~component (iii) comprises an~~ the ophthalmological lubricating agent, [[a]] viscosity enhancing agent, or an agent capable of reducing tear film evaporation is selected from the group consisting of:

hypromellose, Semisynthetic cellulose derivatives, methylcellulose, hydroxyprophylmethylcellulose, carbomer, carmellose, polyvinyl alcohol, polyacrylic acid, povidone, dextran solutions, hyaluronic acid and chondroitin sulphate.

9. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 8~~ claim 1, ~~which~~ wherein said preparation does not contain benzalkonium chloride.

10. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as ~~claim in any one of claims 1 to 9~~ claimed in claim 4, wherein the ~~which comprises an~~ anti-microbial agent is selected from the group consisting of:

lactoferrin, lysozyme, defensin and sIgA;

~~so that~~ and wherein the preparation may be kept at 4 degrees Celsius for up to one month without microbial contamination.

11. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation according to ~~any one of claims 1 to 10, which~~ claim 1, wherein the preparation has a pH ~~in the range~~ of from 6.6 to 8.0.

12. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 11, which~~ claim 1, wherein the preparation is in the form of a solution for use as eye drops.

13 (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 11, which~~ claim 1, wherein the preparation is in the form of a cream, ointment or gel.

14 (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim 12, wherein said solution for use as eye drops has an osmolarity ~~in the range~~ of from 290 mOsm to 320 mOsm.

15. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim 12 ~~or claim 14~~, wherein said solution for use as eye drops has a surface tension ~~in the range~~ of from 40 dyne/cm to 80 dyne/cm.

16. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim 12, ~~claim 14 or claim 15,~~ wherein said solution for use as eye drops has a viscosity ~~in the range~~ of from 5 cps to 50 cps.

17. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in ~~any one of claims 1 to 16~~ claim 1, wherein said preparation is in a single dose container.

18. (CANCELED) ~~A pharmaceutical preparation as claimed in any one of claims 1 to 17 for use as a medicament.~~

19. (CANCELED) ~~A pharmaceutical preparation as claimed in claim 18, wherein said medicament is for the treatment of an ocular surface disorder~~.

20. (CURRENTLY AMENDED) ~~A~~ The pharmaceutical preparation as claimed in claim ~~19~~ 1, wherein said ocular surface disorder is selected from the group consisting of:

dry eye, severely dry eye, scarring, ocular pemphigoid, persistent epithelial defect, acute ocular surface disease, chronic ocular surface disease, infection or inflammation **[[**or**]]** of the eye, neoplastic conditions of the eye and trauma to the eye.

21. (CANCELED) ~~Use of a pharmaceutical preparation as claimed in any one of claims 1 to 17 for the manufacture of a medicament for the treatment of a condition defined in claim 19 or claim 20.~~

22. (CURRENTLY AMENDED) A method of treating an ocular surface disorder in a subject in need of such treatment comprising administering to said subject a therapeutically effective amount of a pharmaceutical preparation as claimed in ~~any one of claims 1 to 17~~ claim 1.

23. (CURRENTLY AMENDED) ~~A~~ The method as claimed in claim 22, wherein the ocular surface disorder is ~~as defined in claim 20~~ selected from the group consisting of dry eye, severely dry eye, scarring, ocular pemphigoid, persistent epithelial defect, acute ocular surface disease, chronic ocular surface disease, infection or inflammation of the eye, neoplastic conditions of the eye and trauma to the eye.

24. (CURRENTLY AMENDED) ~~A~~ The method as claimed in claim 22 ~~or claim 23~~, wherein the subject is a mammal.

25. (CURRENTLY AMENDED) ~~A~~ The method as claimed in claim 24, wherein the mammal is a human.

26. (CANCELED) ~~Use of a pharmaceutical preparation according to any of one claims 1 to 17 as a pharmaceutical vehicle or carrier for an ophthalmological pharmaceutical composition.~~

27. (CANCELED) ~~A pharmaceutical preparation as described herein with reference to any one or more of the examples.~~